IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

NEUROVISION MEDICAL PRODUCTS, INC., Plaintiff, v. MEDTRONIC PUBLIC LIMITED COMPANY; MEDTRONIC, INC.; MEDTRONIC XOMED, INC.; HCA HOLDINGS, INC.; and HEALTHTRUST PURCHASING GROUP, L.P. Defendants.	Case No. 2:16-cv-00127 JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT
AND DEMAND FOR JURY TRIAL

Plaintiff Neurovision Medical Products, Inc. ("Neurovision") files this action against Defendants Medtronic Public Limited Company, Medtronic, Inc., Medtronic Xomed, Inc. (collectively, "Medtronic"), HCA Holdings, Inc. ("HCA"), and HealthTrust Purchasing Group, L.P. ("HPG") (collectively, "Defendants") for infringing U.S. Patent 8,467,844 ("the '844 patent") and U.S. Patent 8,634,894 ("the '894 patent") (together "patents-in-suit").

The patents-in-suit relate back to a provisional patent application dated September 21, 2009 (Provisional Application No. 61/244,402). The patents share a common specification and are entitled "Electrode for Prolonged Monitoring of Laryngeal Electromyography."

Neurovision bases its infringement allegations on each defendant's acts of making, using, offering to sell, selling, and/or importing into the United States infringing products, such as Medtronic's NIM Nerve Monitoring Systems (*e.g.,* NIM TriVantage EMG Endotracheal Tube Product, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, and 8229739; NIM 3.0 Nerve Monitors; and

related nerve monitoring products such as Medtronic's Automatic Periodic Stimulation ("APS") Electrodes).

Neurovision's allegations and claims are as follows:

THE NATURE OF THE ACTION

1. This suit seeks redress for the infringement of patents on inventions representing the culmination of a lifetime (approx. 1973-2016) of research and development in a focused technical area by 69-year old engineer-turned-surgeon Dr. James Rea.

2. When not busy performing over 10,000 surgeries and treating over 40,000 patients over his career as an ear, nose and throat ("ENT") surgeon, Dr. Rea founded a surgical device company with a **primary** mission of empowering ENT surgeons to intra-operatively monitor a nerve called the recurrent laryngeal nerve ("RLN").

3. The focus of Dr. Rea's mission is as remarkable as its longevity. He filed his first patent application for RLN monitoring in 1976. His **most recent** RLN-monitoring patent issued 38 years later in 2014. In the interim, the United States Patent and Trademark Office ("USPTO") awarded Dr. Rea another half-dozen patents focused on improving RLN monitoring.[1]

[1] *A decade and a half ago*, the Wall Street Journal recognized Dr. Rea's *then three decades* of innovation in RLN monitoring:

> "[O]tolaryngologist J. Lee Rea has spent ***nearly 30 years*** studying ways to better protect the recurrent laryngeal nerve. A former electrical engineer, he developed a device that goes a step further than monitoring, and helps doctors locate the nerve so they can both monitor and avoid it. The machine, however, is used only by Dr. Rea and a handful of other physicians around the country. ***'I'm kind of a voice in the wilderness on this subject,'*** Dr. Rea says."

Tara Parker Pope, *Thyroid Surgery May Result in Paralysis of Vocal Cords*, Wall Street Journal, Aug. 10, 2001 (available at http://www.wsj.com/articles/SB997389205713615 75) (attached as Exhibit C).

4. Dr. Rea aptly named his company Neurovision Medical Products ("Neurovision").

5. Today, Neurovision's RLN-monitoring products are used in the operating rooms of elite medical institutions like the Mayo Clinic, New York Presbyterian Hospital, and Emory Healthcare.

6. Neurovision's surgical tools command a cult-like following among surgeons who flock to Dr. Rea to discuss their enthusiasm for Neurovision's tools and product implementations.

7. The RLN is a small and delicate nerve hidden behind the lowest portion of the thyroid gland. Thus, surgeons have trouble seeing it during surgery.

8. To quote defendant Medtronic, "experienced surgeons find it difficult to visually identify the recurrent laryngeal nerve (RLN) or Vagus nerve during thyroid surgery and other neck dissections. Studies show that the rate of RLN injury is underestimated and intraoperative nerve monitoring of the RLN is recommended as a risk-minimizing tool."[2]

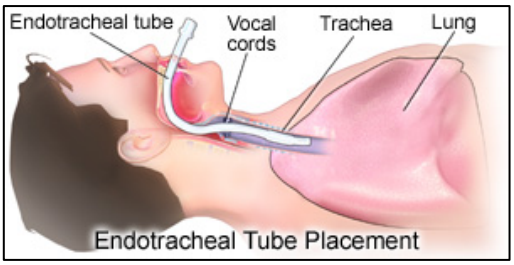
9. In the same WSJ article that noted the pioneering work of Dr. Rea, the chairman of head and neck surgery at Wilford Hall Medical Center at Lackland Air Force Base, Dr. Joseph Brennan, recalled one surgery in which the RLN monitor started beeping as he neared the patient's nerve, which was in an unexpected place. "That monitor clearly saved that nerve for me," said Dr. Brennan.[3]

[2] Excerpt from Medtronic website for one of the accused products—NIM EMG Endotracheal Tubes. http://www.medtronic.com/for-healthcare-professionals/products-therapies/ear-nose-throat/nerve-monitoring-products/nim-nerve-monitoring-systems/related-nerve-monitoring-products/#tab1.

[3] Tara Parker Pope, *Thyroid Surgery May Result in Paralysis of Vocal Cords*, Wall Street Journal, Aug. 10, 2001 (available at http://www.wsj.com/articles/SB99738920571361575).

10. RLN monitoring typically involves five steps:

i. The surgeon inserts an endotracheal tube ("ET tube"), *e.g.*, Medtronic's TriVantage tube, inside the patient's throat ("intubation");

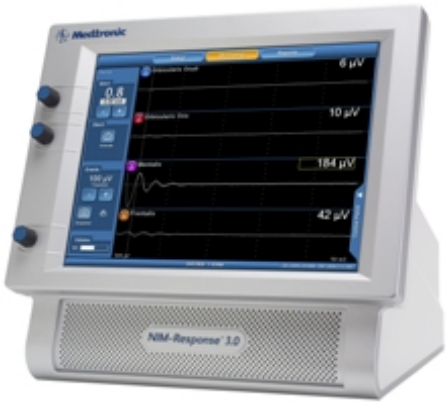


ii. While operating, the surgeon sends a stimulus electrical signal to the operated region, *e.g.*, using Medtronic's APS electrode pictured on the right;

iii. The RLN receives the stimulus signal and, being a nerve, it transmits a response electrical signal;

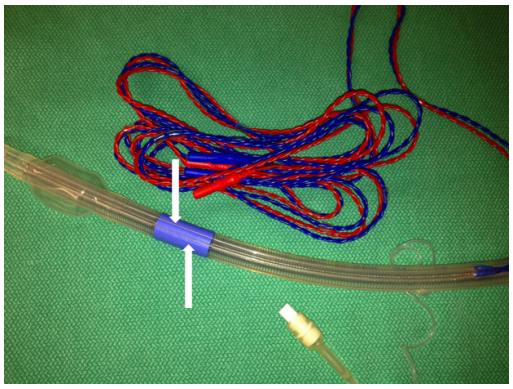
iv. Electrodes associated with the ET tube detect the response signals; and

v. The monitoring system, such as Medtronic's NIM 3.0 Nerve Monitors, sends audio or visual alerts to the surgeon, who can now:
   a) learn the location of the RLN; and
   b) assess its functionality.



11. There were two types of prior art RLN monitoring devices based on how the nerve monitoring electrodes were implemented with the ET tubes:

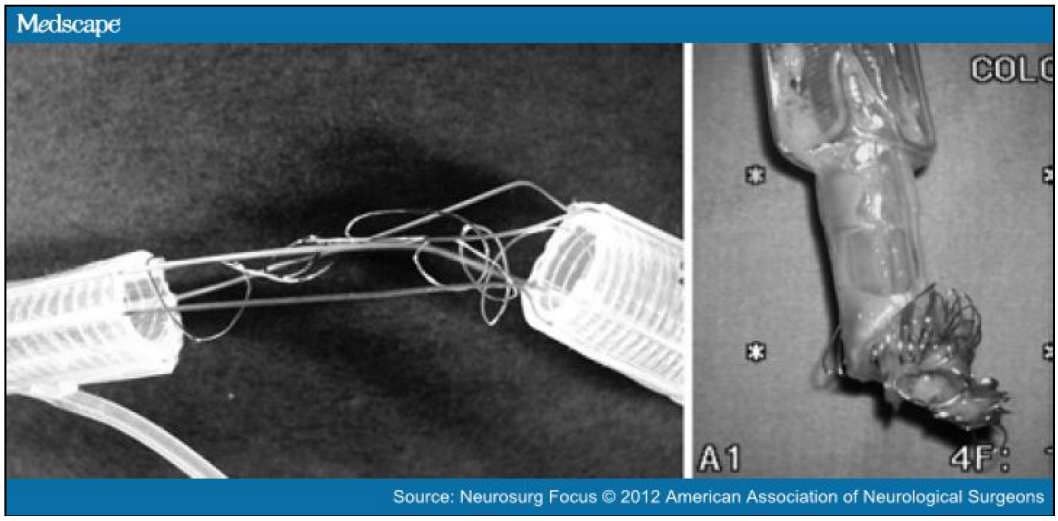
i. **Embedded Approach**: This was Medtronic's prior art approach of pre-manufacturing ET tubes embedded with electrode wires running along the outer surface of the ET tube. Pictured on the right is a Medtronic NIM EMG endotracheal tube with arrows indicating the two stainless steel electrode wires running along the length of the outer surface of the ET tube.



ii. **Adhesive Approach**: These stick-on electrodes could be adhesively attached to any standard ET tube. Pictured on the right is Neurovision's Dragonfly stick-on electrode.

12. Medtronic's prior art embedded approach had numerous documented safety issues. For example, Medtronic's NIM EMG endotracheal tubes contained reinforcement wires within the tube. Surgeons discovered that common medical procedures such as catheter suctioning and non-surgical events such a patient's inadvertent bite could kink or unravel the reinforcement wire. This could result in a mangled mess of wires inside a patient's throat, leading to the buildup of clots or mucus and resulting in airway obstruction.

13. These are actual photographs of device failures involving Medtronic's embedded-wire tubes published in a medical journal:



"Photographs showing airway issues of the [Medtronic] Nerve Integrity Monitor EMG endotracheal tube. **Left**: Use of instrumentation (such as suction catheter) can lead to unraveling of the wires within the endotracheal tube and potential airway compromise …. **Right**: A second example of airway obstruction with the [Medtronic] Nerve Integrity Monitor endotracheal tube, secondary to fibrin clot/mucus buildup on the exposed wires within the lumen of tube." M. Kircher, *et al.*, *Pitfalls in Intraoperative Nerve Monitoring During Vestibular Schwannoma Surgery*, Neurosurg Focus, 33(3):e5 (2012) (cautioning clinicians about Medtronic's NIM EMG products).

14. Another concern pertained to wires running along the outer surface of the tube. Surgeons were worried that these wires could *delaminate* or come apart, directly imperiling the tissues in the neck that this device was intended to safeguard.

15. Apart from these serious safety issues, anesthesiologists and surgeons also complained about the thickness and rigidity of Medtronic's embedded tubes, which limited its functionality:

- **Thickness**: "Indeed, electrodes have been embedded into the material of the tracheal tube (Medtronic Nerve Integrity Monitor (NIM) Standard Reinforced EMG Endotracheal Tube, Medtronix Xomed Inc., Jacksonville, FL, USA), albeit leading to an increase in bulk and external diameter in comparison with equivalent internal diameter tubes." A. Medniuk et al., *Nerve Integrity Monitor Tubes for Thyroid Surgery*, Anaesthesia, Vol. 69, Issue 3, pp. 287-88, Mar. 2014.

- **Rigidity**: "The rigidity of [Medtronic's] NIM tube does not permit easy flexion into an anatomically appropriate curvature, or retention of its shape once curved, compared with other tubes." *Id.*

16. The adhesive approach also had complications. Stick-on electrodes could become displaced during longer surgeries as the adhesive became less adherent in the moist environment of the larynx. This imposed a burden on the anesthesiologist to exercise caution in applying lubricant on the ET tube *after* the electrode was adhesively attached to the tube. *See* F. Telischi, & J. Morcos, *Vestibular Schwannoma: Evidence-based Treatment*, Otolaryngologic Clinics of North America, pp. xvii-xviii, vol. 45, issue 2, April 2012.

17. Both embedded and adhesive approaches necessitated the addition of components to the endotracheal tube not commonly incorporated into this device such as (i) metallic plates, (ii) adhesives, (iii) lead wires, and (iv) structural elements resulting in raised portions on the smooth physical profile of the ET tube. Additionally, these devices introduced structures into the vicinity of the larynx threatening injury to the vocal cords themselves. For this reason, manufacturers did not recommend continuous laryngeal electrode placement for monitoring purposes in excess of eight hours.

18. But this eight-hour restriction necessitated removal and re-insertion of the tubes, which (i) increases risk of injury due to a separate, second airway manipulation; and (ii) deprives the physician of valuable information provided by prolonged and continuous laryngeal monitoring.

19. Medtronic itself criticized the state of the prior art in its U.S. Patent No. 9,037,226 ("the '226 patent"), filed *after* Dr. Rea filed the patents-in-suit. In its patent, Medtronic noted "problems with existing EMG endotracheal [tubes] such as: (1) ridges on the outside of the tube can cause tissue irritation; (2) the tube can shift rotationally during surgery; and (3) the tube wall is too thick." '226 patent at 10:15-16.

Dr. Rea's Inventions

20. Against this backdrop of safety and functionality issues plaguing both the embedded and adhesive approaches, Dr. Rea continued his research and development and invented a revolutionary device that was safer and more functional than any prior art tube in existence.

21. Dr. Rea's inventions overcame problems present in the prior art. For example, one embodiment of Dr. Rea's inventions is devoid of any foreign components embedded inside or attached outside. Instead, in this embodiment, Dr. Rea applied the electrode *directly* to the ET tube by, for example, printing, painting, or spraying the tube's outer surface with electrically conductive paint or ink. Dr. Rea's patents teach that the paint or ink could be a liquid solution or suspension of conductive material, *e.g.*, silver, gold, silver chloride, etc.

22. As shown in the embodiment, Dr. Rea's approach overcame obstacles of the prior art approach of attaching electrodes to ET tubes. Dr. Rea's approach, as shown in one or more of the patented embodiments, was safer and more functional for numerous reasons, including, *e.g.*:

i. the absence of additional parts to the ET tube (*e.g.*, reinforcement wires, metallic plates, adhesives, lead wires, and any structural elements resulting in raised portions of the smooth physical profile of the ET tube's surface) which could delaminate or separate from the inner or outer surfaces of the ET tube, resulting in airway obstructions or injury to the RLN; and

ii. the ability to use the tube for prolonged periods of time (greater than eight hours), obviating repeated extubation/intubation that imperils the very patient it purports to protect.

23. Dr. Rea applied for and was awarded the patents-in-suit for his invention.

Defendants' Infringement

24. Medtronic knew about Dr. Rea's safer, patented approach. Correspondence between Neurovision and Medtronic, as well as the file history for Medtronic's own **later-filed** Patent No. 9,037,226, demonstrates Medtronic's pre-suit knowledge of Neurovision's patents-in-suit:

i. On April 4, 2012, Medtronic disclosed Dr. Rea's patent application resulting in the patents-in-suit to the USPTO;

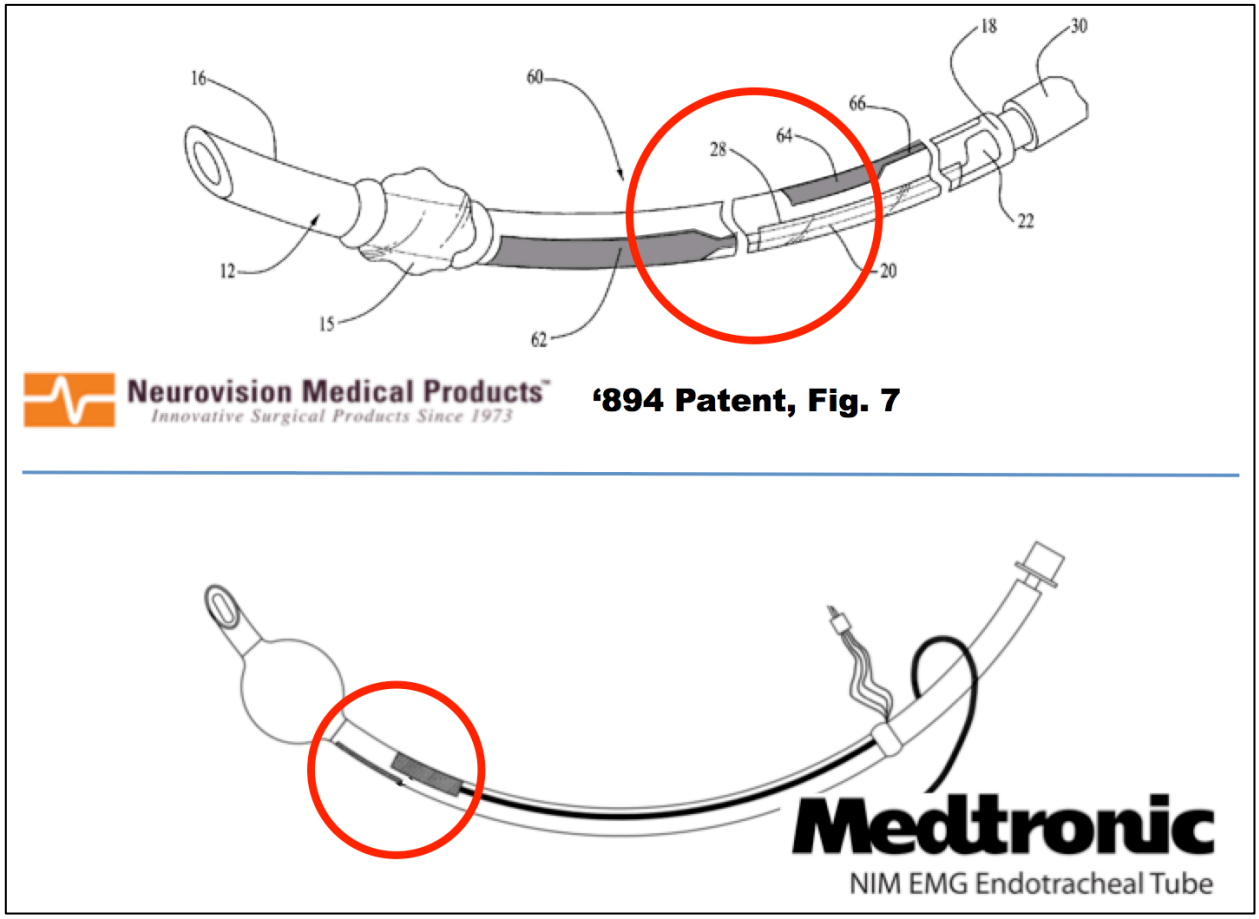
ii. In August 2013, Neurovision executives engaged in discussions with Medtronic about licensing the '844 patent;

iii. On October 9, 2014, Neurovision's counsel, Andrew Kent, wrote an email to Medtronic's counsel, Jim Frias, providing notice of both patents-in-suit; *and*

iv. On March 30, 2015, Medtronic disclosed both patents-in-suit to the USPTO.

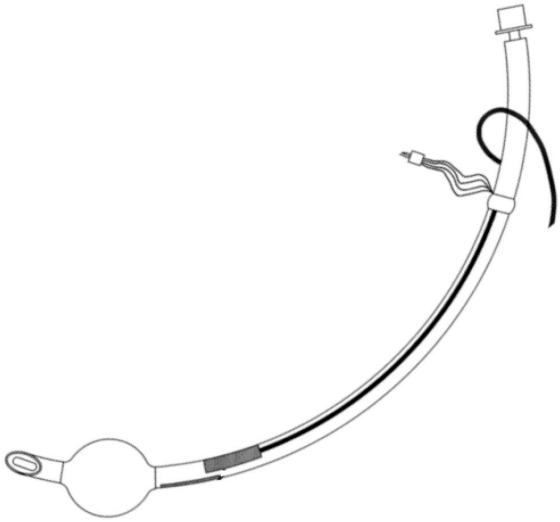
25. Despite this knowledge, Medtronic blatantly copied Dr. Rea's invention taught in the patents-in-suit and unleashed its massive network of sales representatives, flooding the marketplace with its infringing NIM Nerve Monitoring Systems, including its NIM TriVantage tubes, APS Electrodes, and NIM 3.0 Nerve Monitors.

26. For example, claim 1 of the '844 patent recites, *inter alia*: (i) "electrically conductive plate[] applied proximal of the balloon directly to the surface of the tube" and (ii) "traces applied directly to the tube surface and running along the length of the endotracheal tube." Medtronic's infringing TriVantage tube, below, plainly contains: (i) an electrically conductive plate (encircled) applied proximal of the balloon directly to the surface of the TriVantage tube; and (ii) traces applied directly to the tube surface and running along the length of the TriVantage endotracheal tube.[4]



27. When the patents-in-suit issued, Neurovision was manufacturing and marketing its patented invention with its line of Cobra electrodes.

[4] Medtronic's NIM Nerve Monitoring Systems also satisfy all other claim limitations. The images herein are included merely as examples of how the accused products satisfy certain claim limitations.

	
Neurovision's Cobra EMG Tube	Medtronic's Infringing TriVantage Tube

28. Neurovision's Cobra design, like the patent teaches, overcame serious safety issues plaguing prior art products such as Medtronic's dangerous NIM EMG tubes with embedded electrodes, therefore rendering the NIM EMG tubes unacceptable as a non-infringing substitute.

29. Before Medtronic flooded the market with its infringing NIM Nerve Monitoring Systems, including its NIM TriVantage tubes, APS Electrodes, and NIM 3.0 Nerve Monitors, market demand for Cobra electrodes and Neurovision's own nerve monitors was robust and growing. Neurovision was prepared—both financially and operationally—to expand to meet growing market demand. Neurovision's operating cash flow and robust lines of credit provided ample capability to expand its manufacturing and marketing efforts to satisfy even exponential growth in market demand.

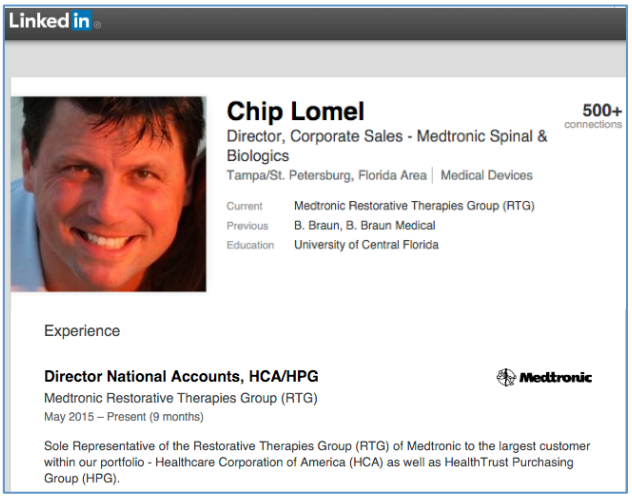
30. By flooding the market with infringing products, Medtronic diverted a significant sales volume away from Neurovision.

31. Today, Medtronic continues to trespass on a majority of the market due to its mammoth sales representative network at considerable continued financial harm to Neurovision.

32. Medtronic disclosed in a filing[5] with the SEC that its infringing sales of the Trivantage EMG tube boosted net growth of 2014 sales to $1.562 billion for its Surgical Technologies business, which Medtronic places in its Restorative Therapies Group.

> Surgical Technologies net sales for fiscal year 2014 were $1.562 billion, an increase of 10 percent over the prior fiscal year. The increase in net sales was driven by continued worldwide net sales growth across the portfolio of ear, nose, and throat ("ENT"), Neurosurgery, and Advanced Energy, partially offset by unfavorable foreign currency translation. Growth was driven by strong sales of navigation, power systems, monitoring, Aquamantys Transcollation, PEAK PlasmaBlade technologies, and Strata adjustable valves. Additionally, net sales growth was positively impacted by the late fiscal year 2013 launches of the Trivantage EMG tube in the U.S. and Indigo high-speed otologic drill internationally.

33. On information and belief, defendants HCA and HPG are Medtronic's largest customers for the TriVantage EMG tube. On a publicly available LinkedIn profile, Chip Lomel, a Director of National Accounts at Medtronic and "Sole Representative of the Restorative Therapies Group," publicly characterizes HCA and HPG as the Restorative Therapies Group's "**largest customer**." That is, the sole representative of the Medtronic group, which sells the infringing TriVantage EMG tube within the United States, admits that HCA and HPG are that group's largest customers.



[5] Medtronic Management's Discussion and Analysis of Financial Condition and Results of Operation, Form S-4, http://www.sec.gov/Archives/edgar/data/1613103/000119312514267867/d741931ds4.htm.

34. HCA and HPG have also refused to allow Neurovision to sell the Cobra to their hospitals in competition to the TriVantage.

THE PARTIES

35. **Plaintiff Neurovision** is a corporation organized under the laws of Missouri with a principal place of business at 2443 Portola Road, Ventura, CA 93003. Neurovision is a practicing entity, and well-known in its industry, with its surgical products used on a daily basis in operating rooms of the world's elite medical institutions like the Mayo Clinic, New York Presbyterian Hospital, and Emory Healthcare.

36. **Defendant Medtronic Public Limited Company** is a corporation organized under the laws of Ireland with a principal place of business at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland. From 1949 to 2014, Medtronic was headquartered in the United States. To avoid taxes on more than $14 billion held overseas, Medtronic moved its headquarters to Ireland and ceased being a United States-based company. To offset personal tax obligations resulting from a tax-inversion acquisition of Dublin-based Covidien, Medtronic reimbursed its top executives to the tune of $63 million while leaving other shareholders with significant capital gains taxes. Medtronic Public Limited Company trades publicly on the New York Stock Exchange with a market capitalization in excess of $100 billion. Medtronic Public Limited Company lists co-defendants Medtronic, Inc. and Medtronic Xomed, Inc. as subsidiaries.

37. **Defendant Medtronic, Inc.** is the original Medtronic before the tax-inversion maneuver that resulted in Medtronic Public Limited Company. Medtronic, Inc. is a corporation organized under the laws of Minnesota with a principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432. Medtronic is one of the world's largest medical device companies. Medtronic has three operating segments: (i) Cardiac and Vascular Group, (ii)

Restorative Therapies Group, and (iii) Diabetes Group. The Restorative Therapies Group includes a Surgical Technologies business, which offers the infringing products, including the TriVantage EMG tubes, the NIM 3.0 Nerve Monitors, and the APS Electrodes, in the United States. Medtronic Inc. is a subsidiary of co-defendant Medtronic Public Limited Company.

38. **Defendant Medtronic Xomed, Inc.** is a corporation organized under the laws of Delaware with a principal place of business at 6743 Southpoint Drive North, Jacksonville, FL 32216. On March 4, 2013, Medtronic Xomed, Inc. initiated a recall for the NIM TriVantage EMG Endotracheal Tube in response to complaints of "cuff leak" or "cuff deflation" and warned that continued use of the recalled product could result in death. Medtronic Xomed, Inc. infringes the patents-in-suit because it makes, uses, sells, offers to sell, or imports the accused products in the United States. Medtronic Xomed, Inc. is a subsidiary of co-defendant Medtronic Public Limited Company.

39. **Defendant HCA** is a corporation organized under the laws of Delaware with a principal place of business at One Park Plaza, Nashville, Tennessee, 37203. HCA is the largest health care services company in the United States. HCA owns and operates over 160 hospitals, over 100 surgery centers, and over 40,000 licensed beds. HCA's general, acute care hospitals provide outpatient services such as outpatient surgery. HCA/HPG is the largest customer of Medtronic's Restorative Therapies Group, which sells the accused products. HCA is the parent of co-defendant HealthTrust Purchasing Group L.P.

40. **Defendant HPG** is a corporation organized under the laws of Delaware with a principal place of business at 155 Franklin Road, Brentwood, Tennessee, 37027. HPG is a group purchasing organization. HPG aggregates market demand from many hospitals and buys the accused products in bulk at a discount, before marking prices up and selling them to individual

hospitals. HPG/ HCA is the largest customer of Medtronic's Restorative Therapies Group, which sells the accused products. HPG is a subsidiary of co-defendant HCA.

JURISDICTION AND VENUE

41. This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction over the claims of patent infringement alleged in this Complaint under 28 U.S.C. §§ 1331 and 1338(a).

42. This Court has personal jurisdiction over Medtronic, HCA, and HPG because each defendant has substantial, systematic, and continuous contacts with this judicial district. Medtronic has filed patent suits in the Eastern District of Texas and has manufacturing facilities in Texas. Medtronic Xomed has facilities in Houston, Texas. Medtronic PLC is a foreign corporation. HCA's annual report states that its facilities are heavily concentrated in Texas, where it has 36 out of its 160+ hospitals and over 10,000 beds. HCA has admitted in previous litigation that it has numerous, continuous, and systematic contacts with the State of Texas, including in the Eastern District of Texas. D.I. 1, 2 of Case No. 2:01-cv-249-TJW.

43. Venue is proper in this judicial district in the Eastern District of Texas pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b) because, among other reasons, each defendant is subject to personal jurisdiction in this district. Further, a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this judicial district.

FACTUAL BACKGROUND

Dr. James Lee Rea

44. Dr. James Lee Rea, the inventor of the patents-in-suit, has lived three lifetimes:

(i) **Innovative electrical engineer** with ten issued medical device patents;
(ii) **Founder and CEO** of a medical device company that develops, manufactures and sells nearly a dozen innovative medical products; and

(iii) **Board-certified head and neck surgeon** with four decades of experience, including over 10,000 surgeries and over 40,000 patients under care.

45. Dr. Rea received a Bachelor of Science degree in Electrical Engineering from the University of Illinois at Urbana-Champaign.

46. After graduation, Dr. Rea worked as an electrical engineer at McDonnell-Douglas Corp. in St. Louis, Missouri.

47. In 1969, Dr. Rea pivoted from electrical engineering to medicine and enrolled at the St. Louis University School of Medicine.

48. After graduating as one of only two engineers in his medical school class, Dr. Rea completed an internship and two residencies, the second with a focus on head and neck surgery.

49. Over the next four decades, Dr. Rea practiced as a head and neck surgeon, treating an estimated 40,000 patients and performing over 10,000 surgical procedures (including over 400 thyroid surgeries).

50. In parallel, over those four decades Dr. Rea founded and built a medical device company from scratch. That company is Plaintiff Neurovision Medical Products.

51. Neurovision's products are the gold standard in each category in which they are sold, and are used in prestigious institutions such as the Mayo Clinic, Emory Healthcare, and New York Presbyterian Hospital.

1976: Dr. Rea, while a medical resident, invents the first laryngeal monitoring device

52. During Dr. Rea's medical residency in the mid-1970s, he learned that surgeons performed thyroid surgery without information about the location of the RLN, injury of which could paralyze the voice box or even kill the patient.

53. Medical technology in the late 1970s did not enable surgeons to monitor, in real time, the proximity of their surgical knife to the RLN during thyroid surgery.

54. On one hand, ENT surgeons—lacking engineering knowhow—were unqualified to conceive, let alone implement, a solution to this problem. On the other hand, electrical engineers—lacking surgical knowhow—lacked awareness, let alone motivation, to solve this problem.

55. Dr. Rea's engineering background enabled him to view the same problem from an electrical engineering perspective.

56. He devised a solution with the following framework: (a) the cutting device used in surgery could double as a channel for the surgeon to transmit a periodic stimulating signal to the local region being operated upon; (b) if the knife was too close to the recurrent laryngeal nerve, the nerve would fire off a unique pattern of electrical signals; (c) electrodes near the laryngeal muscle would detect electrical activity associated with the ensuing contractions; and (d) an audible or visual display output would alert the surgeon of proximity to the laryngeal nerve in real time.

57. With two professors from medical school, Dr. Rea filed an application for what would turn out to be **the very first issued patent** on laryngeal monitoring in 1976—U.S. Patent No. 4,155,353.

Neurovision

58. Tapping into his entrepreneurial spirit, in 1985, Dr. Rea founded RLN Systems, Inc., which would later become Neurovision Medical Products of Ventura, California.

59. Today, Neurovision designs, manufactures, and sells a diverse portfolio of medical products, including numerous patented laryngeal monitoring devices used in surgical procedures. Neurovision's products are depicted in the table below:

Product	Image
Cobra: monitoring electrode on standard endotracheal tube	
Dragonfly: stick-on electrodes	
Nerveana: nerve locator and monitor system, a surgical tool and monitor	
Scorpion: unique instruments enhanced to become monopolar stimulator probes	

Product	Image
DryTouch: suction stimulator probes evacuate fluid to create a dry testing environment for evoked EMG	
Hummingbird: single-use EMG stimulator probes	
Mastodon: subdermal needles for facial nerve monitoring	

60. Neurovision is a growing company. Over the last decade, its sales have grown at a rate of approximately 10-15% per year.

61. Despite Medtronic's vast resources, Neurovision routinely out-performs Medtronic by *inventing* first within the domain of laryngeal electromyography—an inventive space Dr. Rea has dominated for four decades. For all of Medtronic's billions, it could not

synthesize an electrical-engineer-turned-ENT-surgeon with the technical chops of an engineer and the experience of a physician with ten thousand surgeries under his belt.

Neurovision's Patents

62. In exchange for his numerous contributions to the public domain over the years, the U.S. Patent and Trademark Office ("USPTO") awarded Dr. Rea numerous patents (asserted patents in bold):

i. **8,634,894 ("Electrode for Prolonged Monitoring of Laryngeal Electromyography")**
ii. **8,467,844 ("Electrode for Prolonged Monitoring of Laryngeal Electromyography")**
iii. 8,103,339 ("Nerve Stimulator with Suction Capability")
iv. 7,583,991 ("Attached Surface Electrode for Laryngeal Electromyography")
v. 7,379,767 ("Attachable and Size Adjustable Surface Electrode for Laryngeal Electromyography")
vi. 5,178,145 ("Self Retaining Laryngeal Surface Electrode and Method for Independent Identification of Human Recurrent Laryngeal Nerve")
vii. 4,155,353 ("Electrode and Method for Laryngeal Electromyography")

63. Neurovision is the owner of the entire right, title, and interest in and to the '894 patent, entitled "Electrode for Prolonged monitoring of Laryngeal Electromyography" and issued on January 21, 2014. Neurovision holds the exclusive rights to bring suit with respect to any past, present, and future infringement of the '894 patent. A copy of the '894 patent is attached as Exhibit A hereto.

64. Neurovision is the owner of the entire right, title, and interest in and to the '844 patent, entitled "Electrode for Prolonged monitoring of Laryngeal Electromyography" and issued on June 18, 2013. Neurovision holds the exclusive rights to bring suit with respect to any past, present, and future infringement of the '844 patent. A copy of the '844 patent is attached as Exhibit B hereto.

65. Neurovision is informed and believes that Medtronic was well aware of the '894 and '844 patents before the filing of this action. On April 4, 2012, Medtronic disclosed the patent application that resulted in the patents-in-suit to the USPTO during prosecution of its own patent (U.S. Pat. No. 9,037,226). Later in the same prosecution, on March 30, 2015, Medtronic disclosed both patents-in-suit to the USPTO. Further, in August 2013, Neurovision's executives held licensing discussions with Medtronic regarding the '844 patent. On October 9, 2014, Neurovision's counsel, Andrew Kent, emailed Medtronic's chief counsel, Jim Frias, informing Medtronic about the patents-in-suit.

Teachings of the Patents-in-Suit

66. As described in the specification, the patents-in-suit teach, for example, printing, painting, or spraying electrodes on the surface of the endotracheal tube using conductive ink or paint.

67. The patents-in-suit teach numerous exemplary materials that could serve as electrodes, such as, *e.g.,* finely divided particles or flakes of silver, silver salts like silver chloride, silver oxide, gold, copper, copper chloride, platinum, carbon, or graphite.

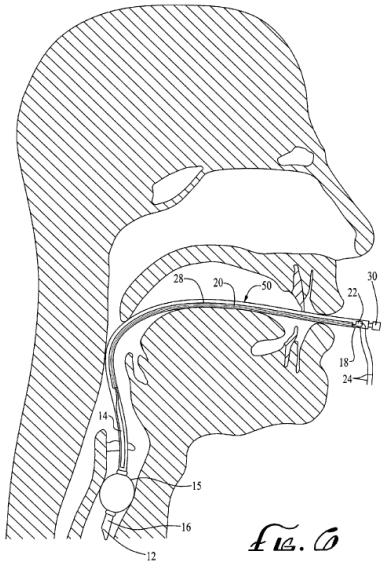


FIG. 6

68. The patents-in-suit also teach, *e.g.,* the respective roles and relative positioning of a retention balloon, electrically conductive electrode plates, electrically conductive traces, conductive pads, leads, monitoring equipment, and insulating material.

69. The patents-in-suit contain numerous exemplary diagrams, such as Figure 6 in both patents, depicting and explaining the role of various aspects of Dr. Rea's laryngeal electrode assembly.

70. The patents-in-suit teach, *e.g.,* that tubes could be manufactured using polyvinylchloride (PVC), rendering the resulting tubes flexible. This was advantageous over prior art techniques like Medtronic's embedded-wires approach, which could not be implemented using PVC. Surgeons complained about the rigidity of Medtronic's embedded tube.

71. The patent specification of the patents-in-suit enriches the public domain by not only disclosing a blueprint of how to recreate the claimed inventions, but also explaining how the inventions could be used to avoid injury to the recurrent laryngeal nerve.

FIRST CLAIM FOR RELIEF
(Infringement of U.S. Patent 8,467,844)
(Against All Defendants)

72. Neurovision realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

73. Neurovision is the owner of the entire right, title and interest in and to the '844 patent.

74. Neurovision is informed and believes, and on that basis alleges, that Medtronic, HCA, and HPG have infringed and are currently infringing one or more claims (*e.g.,* claim 1) of the '844 patent, in violation of 35 U.S.C. § 271.

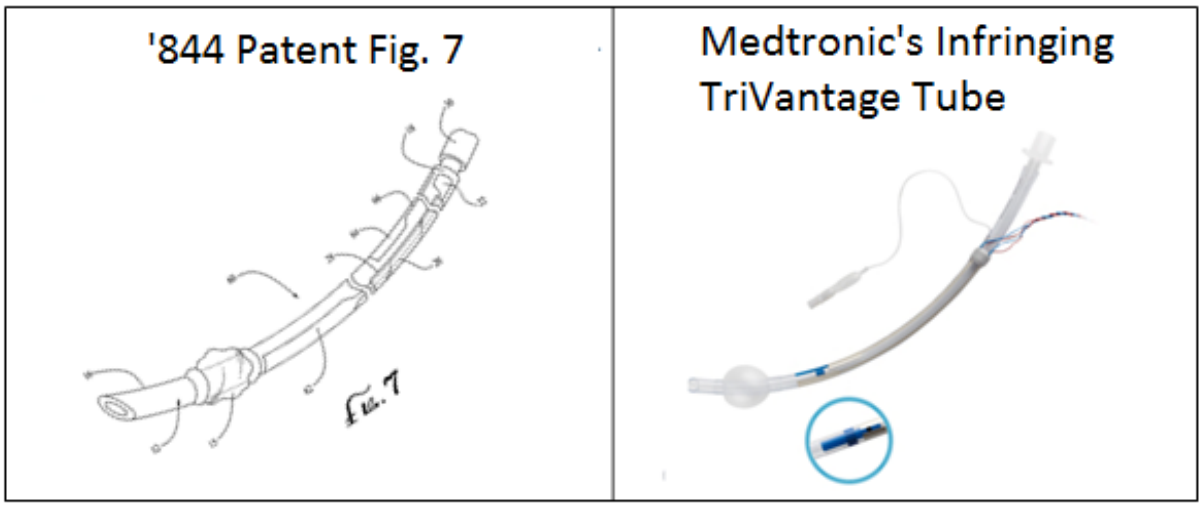
75. Medtronic, HCA, and HPG infringe literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736,

8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS Electrodes, and related products and/or processes falling within the scope of one or more claims, including claim 1 of the '844 patent reproduced below:

> A device for use in monitoring electrical signals during laryngeal electromyography comprising:
>
> an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface one or more electrically conductive electrode plates applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrode plates,
>
> said tube having on its surface electrically conductive traces connected to or integral with the electrode plates, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal end thereof,
>
> conductive pads connected to or integral with the conductive traces, the pads applied directly to the tube surface at the proximal end of the endotracheal tube, and
>
> electrical leads connected to the pads, said leads adapted to connect to monitoring equipment,
>
> the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode plates to a point adjacent the conductive pads
>
> wherein a first of said electrode plates is located proximal of the balloon and positioned to contact the vocal cords when placed within the trachea and a second electrode plate is located further proximal thereof and positioned to contact the tongue when the first electrode plate is positioned to contact the vocal cords.

76. Medtronic's acts of making, using, selling, offering to sell, and importing infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS Electrodes, and related products and/or processes satisfy, literally or under the doctrine of

equivalents, each and every claim limitation, including without limitations claim 1 of the '844 patent.



77. HCA's and HPG's acts of using, selling, offering to sell, and importing infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS Electrodes, and related products and/or processes, satisfy, literally or under the doctrine of equivalents, each and every claim limitation, including without limitation claim 1 of the '844 patent.

78. Medtronic's, HCA's, and HPG's acts of infringement have caused damage to Neurovision in an amount to be proven at trial. Consequently, Neurovision is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

79. Neurovision has suffered irreparable injury as a direct and proximate result of Medtronic's, HCA's, and HPG's acts of infringement for which there is no adequate remedy at law. Unless Medtronic, HCA, and HPG are enjoined, Neurovision will continue to suffer such irreparable injury as a direct and proximate result of the conduct of Medtronic, HCA, and HPG.

80. On information and belief, Medtronic knew of the ’844 patent as early as August 2013, if not earlier. In August 2013, Neurovision and Medtronic held discussions concerning the ’844 patent. *See* Ex. C. Subsequently, on March 30, 2015, Medtronic disclosed the ’844 patent to the USPTO during prosecution of its own patent, U.S. Patent No. 9,037,226.

81. Medtronic undertook its activities of making, using, offering for sale, selling, and/or importing unlicensed products and services despite being aware of an objectively high likelihood that it was infringing the valid ’844 patent. As such, Medtronic willfully infringed the ‘844 patent.

82. Given the facts of this case, Neurovision is further entitled to enhanced damages of three times the amount found or assessed under 35 U.S.C. § 284.

SECOND CLAIM FOR RELIEF
(Infringement of U.S. Patent 8,634,894)
(Against All Defendants)

83. Neurovision realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

84. Neurovision is the owner of the entire right, title and interest in and to the ’894 patent.

85. Neurovision is informed and believes, and on that basis alleges, that Medtronic, HCA, and HPG have infringed and are currently infringing one or more claims (*e.g.,* claim 1) of the ’894 patent, in violation of 35 U.S.C. § 271.

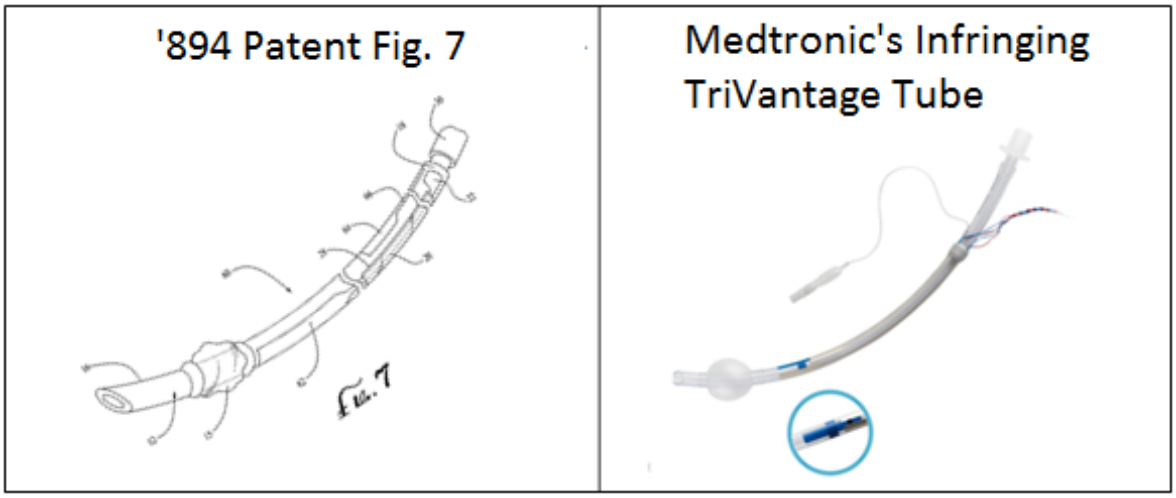
86. Medtronic, HCA, and HPG infringe literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736,

8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS Electrodes, and related products and/or processes falling within the scope of one or more claims, including claim 1 of the '894 patent, reproduced below:

> A device for use in monitoring electrical signals during laryngeal electromyography comprising:
>
> an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface first and second electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of said electrically conductive electrodes positioned to contact the vocal cords, the second electrode positioned to contact tissue, nerves and muscle in the trachea or the tongue when the tube is positioned in the trachea,
>
> said tube having on its surface first and second electrically conductive traces, said traces electrically isolated from each other, each trace connected to or integral with an electrode, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal portion of the tube,
>
> a proximal connection point connected to or integral with each of the conductive traces, the connection points applied directly to the tube surface at a proximal end of the traces on the endotracheal tube, and
>
> electrical leads connected to the connection points, said leads adapted for connection to monitoring equipment,
>
> the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrodes to a point adjacent the connection points.

87. Medtronic's acts of making, using, selling, offering to sell, and importing infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS Electrodes, and related products and/or processes satisfy, literally or under the doctrine of

equivalents, each and every claim limitation, including without limitation claim 1 of the '894 patent.



88. Medtronic's infringing activities also comprise directing or controlling anesthesiologists and surgeons to place the accused endotracheal tubes by intubating patients as part of certain surgical procedures, and to monitor the electrical signals received from the electrodes on the surface of the accused endotracheal tube. Medtronic's "Product Information and Instructions" for the NIM EMG Endotracheal Tube, for example, specifically require, *inter alia*, that anesthesiologists and surgeons "[i]ntubate the patient per the procedure for non-reinforced endotracheal tubes," and "[u]se the EG monitor to measure electrode impedance and imbalance." The Product Information and Instructions explain that "[f]or safe and accurate EMG monitoring, proper handling, insertion and placement of electrodes and probes is critical," and Medtronic conditions its product warranty by indicating that "the following condition[] must be met: … The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling." Medtronic directs or controls the acts of anesthesiologists and surgeons in such a manner as to condition use of the accused products to continuously monitor laryngeal musculature upon the performance of proper

placement and monitoring activities, and establishes the manner and timing of the performance of such acts during certain surgical procedures.

89. HCA's and HPG's acts of using, selling, offering to sell, and importing infringing products, such as, *e.g.,* the NIM TriVantage EMG Tube, including without limitation Product Numbers 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, 8229739, used in conjunction with the NIM 3.0 Nerve Monitors, and APS electrode, and related products and/or processes satisfy, literally or under the doctrine of equivalents, each and every claim limitation, including without limitation claim 1 of the '894 patent.

90. Medtronic's, HCA's, and HPG's acts of infringement have caused damage to Neurovision in an amount to be proven at trial. Consequently, Neurovision is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

91. Neurovision has suffered irreparable injury as a direct and proximate result of Medtronic HCA, and HPG's acts of infringement for which there is no adequate remedy at law. Unless Medtronic, HCA, and HPG are enjoined, Neurovision will continue to suffer such irreparable injury as a direct and proximate result of the conduct of Medtronic, HCA, and HPG.

92. On information and belief, Medtronic knew of the '894 patent as early as October 2014, if not earlier. On October 9, 2014, Neurovision's counsel, Andrew Kent, emailed Medtronic's Vice President and Chief Counsel, Jaime A. Frias, providing notice of the existence of the '894 patent. Ex. C. The email included an attached copy of the '894 patent. Subsequently, on March 30, 2015, Medtronic disclosed the '894 patent to the USPTO during prosecution of its own patent, U.S. Patent No. 9,037,226.

93. Medtronic undertook its activities of making, using, offering for sale, selling, and/or importing unlicensed products and services despite being aware of an objectively high

likelihood that it was infringing the valid ’894 patent. As such, Medtronic willfully infringed the ‘894 patent.

94. Given the facts of this case, Neurovision is further entitled to enhanced damages of three times the amount found or assessed under 35 U.S.C. § 284.

PRAYER FOR RELIEF

Neurovision requests that the Court enter judgment as follows:

A. That Medtronic has directly infringed the ’844 and ’894 patents;

B. That HCA and HPG have directly infringed the ’844 and ’894 patents;

C. That Medtronic and any of its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly, be enjoined from infringing the ’844 and ’894 patents;

D. That HCA, HPG and any of their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly, be enjoined from infringing the ’844 and ’894 patents;

E. That Medtronic and any of its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly, deliver to Neurovision all products that infringe the ’844 and ’894 Patents for destruction at Neurovision’s option;

F. That HCA, HPG and any of their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, or acting in concert with any of them directly or indirectly,

deliver to Neurovision all products that infringe the ’844 and ’894 Patents for destruction at Neurovision’s option;

G. That Medtronic be ordered to pay damages to Neurovision, together with costs, expenses, pre-judgment interest and post-judgment interest as allowed by law;

H. That HCA and HPG be ordered to pay damages to Neurovision, together with costs, expenses, pre-judgment interest and post-judgment interest as allowed by law;

I. That Medtronic be ordered to provide an accounting;

J. That HCA and HPG be ordered to provide an accounting;

K. That Medtronic be ordered to pay supplemental damages to Neurovision, including without limitation interest;

L. That HCA and HPG be ordered to pay supplemental damages to Neurovision, including without limitation interest;

M. That Medtronic’s infringement be adjudged willful;

N. That the damages for Medtronic be increased under 35 U.S.C. § 284 to three times the amount found or assessed;

O. That the damages for HCA and HPG be increased under 35 U.S.C. § 284 to three times the amount found or assessed;

P. That the Court enter judgment against Medtronic, and in favor of Neurovision in all respects;

Q. That the Court enter judgment against HCA and HPG, and in favor of Neurovision in all respects;

R. That the Court determine this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys’ fees and costs to Neurovision is warranted in this action; and

S. For any such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Neurovision Medical Products, Inc. hereby demands a trial by jury on all issues raised in this Complaint that are so triable by right.

Dated: February 8, 2016

RUSS AUGUST & KABAT

/s/ *Benjamin T. Wang*

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Attorneys for Plaintiff Neurovision Medical Products, Inc.

CERTIFICATE OF SERVICE

I hereby certify that the counsel of record who are deemed to have consented to electronic service are being served on February 8, 2016 with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3). Any other counsel of record will be served by electronic mail, facsimile transmission and/or first class mail on this same date.

/s/ *Benjamin T. Wang*____
Benjamin T. Wang